【P-46】

Risk Assessment Diethylhexyl phthalate released from PVC Medical Devices based on Reproductive Toxicity

Lee, HM, Yoon, EK, Lee, GY, Kim, HJ, Yang, JS, Yang, KH, Han,SY[1], Jang, SY[2], Choi, DW[2]

Risk Assessment Division, National Institute of Toxicological Research

[1]Endocrine Toxicology Division, National Institute of Toxicological Research

[2]Medicinal Chemistry Division, Korea Food and Drug Administration

Diethylhexyl phthalate (DEHP) was known as endocrine disrupter revealing reproductive / developmental toxicity. For a long time, risk due to DEHP released from PVC medical devices was became an issue for patient receiving blood bag, iv injection solution like saline and Hartman's solution. This study was conducted to suggest permissible intake level (PIL) of DEHP based on reproductive toxicity, to quantify daily intake level of DEHP can be exposed to patient through various medical treatment and to estimate risk values of DEHP released from PVC medical devices. Estimating daily intake of DEHP through various medical treatment was done by considering monitoring data produced from Endocrine Disruptors Program (1999~2002) and real exposure scenario. Human daily intakes of the DEHP released from PVC medical devices were estimated as 6.67×10^{-5}~1.15×10^{-2}mg/kg/day in single injection of iv solution, 2.72×10^{-3}~6.09×10^{-2}mg/kg/day in single injection of blood product, and 1.20×10^{-3}~6.97×10^{-2}mg/kg/day in combined injection of iv solution and blood product. The suggested permissible intake levels (PIL) that occurrence of reproductive toxicity would not be expected, were 0.14 mg/kg/day for DEHP. The hazard indeces produced by comparing PIL with human daily intake were 0~0.08 in single injection of iv solution, 0.02~0.43 in single injection of blood product, and 0.03~0.49 in combined injection of iv solution and blood product. Resulted all risk values means the occurrence of reproductive toxicity would not be expected in current exposure status.